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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/714,156 | 11/14/2003 | Mitchell I. Kirschner | 718689 | 2373 |

7590

06/08/2005

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,156

Applicant(s)

KIRSCHNER ET AL.

Examiner

Frank I. Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Examiner withdraws the finality of the prior Office Action in view of the new grounds of rejection herein. The rejection of claims 63, 71 under 35 USC 112 is moot due to cancellation of said claims. Examiner withdraws the 35 USC 103 rejection over Hermelin et al. or Abbruzzese, each in view of the acknowledged prior art, Opheim, Manufacturing Chemist & Aerosol News and Cuca in view of the fact that the effective filing date of May 27, 1999 with respect to the pending claims predates the effective filing date of Hermelin et al. and Opheim. However, Examiner makes the following observations. The claims are directed to compositions, as such, neither Applicant's intended use nor Abbruzzese's intended use have a bearing on motivation so long as there is motivation to prepare the composition regardless of its intended use. Further, the level of amino acids is immaterial as neither the claims nor Applicant's intended use exclude the presence amino acids from the claims. Whether members of medical community agree or disagree with a medical treatment does not control the determination of obviousness. See *In re Jansen*, 187 USPQ 743 (CCPA 1975). There was no hindsight picking or choosing from components as both the fatty acids and calcium are chosen for their disclosed nutritional benefits. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 65 USPQ 297 (1945) ("Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 65 USPQ at 301.). Abbruzzese specifically discloses that fish oils are a source of the fatty acids, as such, there is motivation to use fish oils with the expectation that they would provide the fatty acids in the composition (Column 7, lines 43-68). Although PEG as a vehicle is disclosed in Cuca, Cuca also discloses the use of vegetable oil as a vehicle (Column 3, lines 14, 15). As such, contrary to Applicant's

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arguments, the use of vegetable oil instead of PEG is obvious. As Examiner has indicated in the prior Office Action, the written description requirement is separate and distinct from the enablement requirement. As such, whether or not the '559 application would enable one of ordinary skill in the art to make and use products containing omega-3-fatty acids, the '559 application lacks written description of the omega-3-fatty acids. However, the fact that the '559 application lacks written description of omega-3-fatty acids does not overcome the 35 USC 103 rejection as omega-3-fatty acids are fatty acids. Therefore, Manufacturing Chemist & Aerosol News which discloses omega-3-fatty acids meets the claim limitation of "at least one fatty acid." Notwithstanding the same, Examiner withdraws the rejection over the remaining references in favor of and as being duplicative of the prior art rejections set forth below.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 26, 28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Borkan et al. (US Pat. 4,935,243) or

Borkan et al. expressly disclose a soft gelatin capsule containing calcium carbonate and vegetable oil falling within the scope of applicant's claims (Column 7, lines 30-68, Column 8, lines 1-10). Vegetable oil contains fatty acids.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al. (US Pat. 4,935,243) or Kern et al. (US Pat. 2, 491,452), each in view of Chang et al. (US Pat. 4,874,629) and WO 97/04668.

Borkan et al. disclose a soft gelatin capsule containing calcium carbonate and vegetable oil (Column 7, lines 30-68, Column 8, lines 1-10). It is disclosed that the capsule fill material can include nutritional supplements such as minerals and fatty acids dispersed in or dissolved in a non-toxic liquid base such as a vegetable oil, such as safflower oil, sunflower oil and soybean oil (Column 5, lines 39-55, Column 6, lines 50,51).

Kern et al. disclose a soft gelatin capsule containing calcium pantothenate, glucono-delta-lactone and the use of vegetable, such as soy bean, and/or fish liver, such as tuna liver oils, in a matrix for the active ingredients which act to protect the instable elements (Columns 3,4). Capsules are disclosed containing calcium pantothenate and cottonseed oil (Table I, Table II)

Chang et al. disclose that polyunsaturated fatty acids of vegetable origin have an hypocholesterolemic effect and that omega-3 fatty acids from fish oils have high pharmacological and dietary potential, however, that fish oils are subject to degradation (Column

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1). It is disclosed that the stability of the fish oils can be increased by combining with a vegetable oil, such as sunflower or soybean oil (Column 5, lines 40-46, Column 6, lines 1-12). Examples of fish oils include sardine and menhaden oil (Column 3, lines 55-68).

WO 07/04668 disclose the combination of at least one representative of the group of trace elements and minerals, such as calcium in the form of an inorganic, such as calcium carbonate, or an organic compound and at least one representative of the unsaturated fatty acids from vegetable or animal oils, such as fish oil, in soft gelatin capsules (Pg. 7, lines 21-29, Pg. 8, lines 1-5, 15-31, Pg. 10, lines 34-37, Pg. 11, lines 1-15, Pg. 13, lines 10-25). Examiner notes that US 6,471,969 is the 371 of WO 07/04668.

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of a fatty acid derived from a marine source. However, the prior art amply suggests the same as the prior art discloses the preparation of soft gelatin capsule containing a fatty acid, that pharmacologically and dietary fatty acids of high potential come from fish oils and that the stability of the fish oils can be increased by addition of vegetable oils. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior as above with the expectation that the combination would provide mineral supplementation and/or treatment or minimization of stomach upset and health benefits of polyunsaturated fatty acids.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

June 7, 2005



SABIHA QAZI, PH.D
PRIMARY EXAMINER